UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Review of the Fish Early-Life Stage Ecotoxicity Data for PMN P08-0508-0509

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[redacted]

The objective of this memorandum is to provide a detailed review of the submitted fish early-life stage ecotoxicity data for PMN P08-0509 also identified by the submitter as [redacted].

Background

PMN P08-0508 and P08-0509 were submitted by DuPont Fluoroproducts on 31 July 2008, and are respectively the free acid and ammonium salt of perfluorinated propanoic acid linked via an ether bond to perfluorinated propane. The acid PMN (P08-0508) is intended as a precursor to the salt [redacted]) and for [redacted] as a polymerization aid [redacted]. The ammonium salt (P08-0509) is intended for use [redacted].

Physico-chemical properties

P08-0508 is a [redacted] at room temperature

[redacted]

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MW = 330
S = 205 mg/L (estimated)
[redacted]
log Kow of 3.66 (estimated)
log Koc of 2.08 (estimated)
fish BCF of 0.50 (estimated)

P08-0509, the ammonium salt of the PMN, is [redacted] room temperature.
MW = 347.
dispersible in water.
[redacted]
log Kow of 0.78 (estimated)
log Koc of 2.91 (estimated)
fish BCF of 0.50 (estimated)

The FOCUS meeting on July 24th, 2008 decision for this PMN was a Standard Review to be conducted with a risk assessment division disposition date of October 15, 2008. The ecotoxicity risk assessment is indicated below:

Ecotoxicity hazard profile

Acute ecotoxicity information was available for these two PMN's. No toxicity occurred in fish (rainbow trout), daphnia, or algae at concentrations up to 100 mg/L. In addition, ecotoxicity was predicted using ECOSAR (v. 0.99g) based on the category anionic surfactants of C8 chain-length and with a carboxylic acid functional group. ECOSAR predictions were in approximate agreement with the actual test data. From the test data, a concentration of concern of 969 µg/L (ppb) was assigned by dividing 96.9 mg/L by a factor of 10 to simulate a chronic effect level, then dividing again by another assessment (uncertainty) factor of 10, which yields a chronic Concentration of Concern (CoC) value of 0.969 mg/L or 969 µg/L (ppb). To derive an acute CoC, 96.9 mg/L is divided by a factor of 6.5, yielding 14.907 mg/L or 14, 907 µg/L.

ECOSAR predictions profile

(P) predicted

Fish 96-h LC50 (P)	60.0 (P)
Daphnid 48-h LC50	47.0 (P)
Green algae 96-h EC50	12.0 (P)
Fish chronic	9.0 (P)
Daphnid chronic	7.0 (P)
Algae chronic	6.0 (P)

Test Data Results

(M) measured; all values are in mg/L.

Fish 96-h LC50 (*Oncorhynchus mykiss*)	96.9 (M)
Daphnid 48-h LC50 (*Daphnia magna*)	> 102 (M)
Green algae 72-hr EC50 (*Pseudokirchneriella subcapitata*)	> 106 (M)

Exposure assessment

Surface water concentrations were estimated using EPA's predictive model. EFast shows that the highest average concentration (7Q10) was approximately [redacted] for multiple scenarios (D. Sherer 2008).

Risk characterization

Because the maximum predicted stream concentration was below the measured chronic CoC of 969 µg/L and did not exceed this value any day of the year, the risk of chronic toxicity to the aquatic environment is low (predicted CoC determined from the ECOSAR data results agreed well). Because none of the predicted stream concentrations approached the acute CoC of 14,907, the risk of acute toxicity to the aquatic environment is low (Cragg 2008).

Consent order

The risk characterization determined PMN P08-0508/0509 represents a low risk to the aquatic environment, however, a consent order was issued on November 13, 2008. This consent order explicitly states that "...The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order." [Therefore,] "The Company is prohibited from manufacturing or importing the PMN substances beyond the following aggregate manufacture and import volumes of both PMN substances combined ("the production limits"), unless the Company conducts the following studies and submits all final reports and underlying data in accordance with the conditions specified in this Testing section (PMN P08-0508/0509 Consent Order 2008).

Production Limit	Study	Guideline
[redacted] kilograms	4) Fish Early Life Stage Toxicity	OPPTS 850.1400

Submitted protocol

A draft protocol for the Fish Early Life Stage Toxicity test (OPPTS 850.1400) was submitted for P08-0508/0509 on June 17th, 2009. The protocol was submitted based on the previous information regarding the risk assessment outcome and signed consent order from DuPont Fluoroproducts.

Fish Early Life-Stage Test Data Results

Test data results for PMN P08-0509 were received on December 13, 2010 and are reviewed herein. Due to the nature of the PMN P08-0508/0509 as a perfluorinated compound, testing of the ammonium salt, P08-0509 was conducted for the Fish Early

Life-Stage Test (FELS). The test substance for PMN P08-0509 is a [redacted] and is described as 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propionic acid, ammonium salt (CASRN 62037-80-3). The solubility of the test substance is 218 mg/L. The test was conducted in 2010 by E.I. du Pont de Nemours and Company Laboratories [redacted]. A signed quality assurance statement and GLP statement were also provided.

The test was conducted according to the OCSPP 850.5400 Fish Early-Life Stage Toxicity test and the OECD Guideline for Testing of Chemicals Section 2 (Part 210): Fish, Early-Life Stage Toxicity Test. All comments made by EPA in the protocol review were addressed in the test data results except for reference to the difficult to test substance guidance document either OCSPP 850.100 or OECD Series on Testing and Assessment No. 23 - Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. Twenty-four hour post-hatch Rainbow trout (*Oncorhynchus mykiss*) were exposed for 90 days to the PMN material P08-0509 in an intermittent flow test. Eighty embryos total were exposed per test concentration (20 embryos per cup, 2 cups per replicate, and 2 replicates per concentration). Test solutions were supplied to each replicate test chamber from a diluter system (checked every 24 hours during the test) at a turn-over rate of 30 L per replicate per day (guideline recommended turn-over rate of five, 6L test solution volumes per day).

Embryos and alevins were held in relative darkness until day 30 for a light:dark period of 16:8 with a 30 minute transition to simulate dusk and dawn. Each embryo cup was oscillated at ~ 4 rpm and were inspected daily for fertilized eggs, and damaged or fungus-infected eggs. Surviving alevins and fingerlings were thinned to 15 per replicate on day 46 of exposure after swim-up had begun in the control replicates. All test concentrations were maintained at guideline values for water quality parameters: temperature 11.8 – 12.9 °C, pH = 7.4 – 8.3, DO = 5.8 and 10.3 mg/L, Alkalinity = 81 – 92 mg/L $CaCO_3$, Hardness = 100 – 166 mg/L $CaCO_3$, and conductivity = 180 – 269 µhmos/cm.

Observations were made for mortality of eggs, hatching, swim-up, survival and abnormalities from hatching to thinning on day 46, and survival and abnormalities from thinning to test end.

Nominal test concentrations [redacted] were 0, 0.63, 1.25, 2.50, 5.00, and 10 mg/L. Mean, measured concentrations were 0, 0.651, 1.08, 2.16, 4.66, and 8.89 mg/L and were 86 – 103 % of nominal. Analytical verification of the test concentrations were made on days 0, 1 and weekly until test end at day 90 with HPLC methods with an LOD (limit of detection) and LOQ (limit of quantification) of 0.0005 and 0.005 mg/L, respectively.

No statistically significant effects were observed among the test concentrations for any of the endpoints observed. The test is considered valid. The endpoints are all based on egg mortality, hatching, swim-up, and survival.
90 day EC_{50} > 8.89 mg/L
90 day LOEC = 2.16 mg/L

90 day NOEC = 1.08 mg/L

Concentration of Concern

To determine a concern concentration, the geometric mean of the LOEC and NOEC will be used due to the designation of the values indicated for the EC_{50} endpoints from the test as ">". The geometric mean of the 90 day LOEC and NOEC is 1.53 mg/L.

The Chronic CoC = 1.53 mg/L divided by an assessment (uncertainty) factor of 10 = 0.153 mg/L or 153 µg/L (ppb).

The Acute CoC = 1.53 mg/L divided by an assessment (uncertainty) factor of 10 = 0.153 mg/L. This value is then multiplied by a chronic to acute ratio of 6.5 for fish = 994.5 µg/L or 995 ppb.

Conclusion

Previous surface water concentrations (highest average concentration; 7Q10) were determined from a preliminary concentration of concern estimated from ECOSAR (v. 0.99g). A subsequent concern concentration derived from the chronic daphnid test (reviewed in a separate report, S. Pollack 2010) was determined to be 582 ppb. However, the most sensitive species is fish as a result of the current review. An additional, updated exposure assessment will need to be run implementing the newly derived CoC (153 ppb; from the fish early-life stage test reviewed) to determine if PMN P08-0508/0509 is a significant chronic risk to aquatic organisms.

References

1) Risk Assessment for PMN P08-0508/0509 (S. Cragg, October 15, 2008).

2) Consent Order for PMN P08-0508/0509 (November 13, 2008).

3) Post-Focus Exposure report for PMN P08-0508/0509 (D. Sherer, October 6, 2008).

4) U.S. EPA. 1996. Ecological Effects Test Guideline OPPTS 850.1400: Fish Early Life-Stage Toxicity Test (EPA 712-C-96-121). U.S EPA Office of Prevention, Pesticides and Toxic Substances.

5) OECD Guideline for Testing of Chemicals Section 2 (Part 210) Fish, Early-Life Stage Toxicity Test (1992).

6) FINAL_Daphnid Chronic Test Data Review for PMN P08-0508-0509. (S. Pollack April 4, 2010).